

Formal Matters

Claim 72 has been revised to refer to emphasize a feature of the claimed subject as originally presented. No change in claim scope is intended or believed to have occurred. Support is provided at least by claim 80 and on pages 20-24 of the instant application.

Claims 73, 74, 78, 79, 81, and 84-89 have been amended to correspond better with claims 72 and 80 from which they depend by referring to “an altering composition” as well as “cells” as recited in claims 72 and 80. Support is provided at least by claims 72 and 80 as previously presented, and no change in claim scope is intended or has occurred. The claims have also been amended to

Claim 80 has been amended, along with the addition of new claims 90 and 91, to expressly refer to the claimed methods as practiced *in vivo* or *ex vivo*. Support is provided at least on page 31 and page 33, lines 11-24, of the instant application, and no change in claim scope of claim 80 is intended or has occurred.

No new matter has been introduced, and entry of the amendment is respectfully requested.

Remarks

The Examiner has required restriction between Groups I (claim 72); Group II (claims 73-76); Group III (claim 77); Group IV (claim 78); Group V (claim 79); Group VI (claim 80); Group VII (claims 81-84); Group VIII (claim 85); Group IX (claim 86); Group X (claim 87); Group XI (claim 88); and Group XII (claim 89). As addressed in detail below, Applicants hereby elect with traverse Group I.

Applicants strongly traverse the presentation of Group I (claim 72) “as solely drawn to an *in-vitro* method”. Applicants respectfully submit that it is their right to define the subject matter of a claim, and that the language of claim 72 makes no limitation to being practiced “*in vitro*”. To emphasize this point, Applicants have presented new claims 90 and 91, which are both directly dependent from claim 72. Claim 90 is directed to the methods of claim 72 as practiced “*ex vivo*” while claim 91 is directed to the methods of claim 72 as practiced “*in vivo*.”

New claims 90 and 91 also emphasize the nature of claim 72 as a “genus claim” to which claims 90 and 91 are species. If the Restriction Requirement setting forth Group I (claim 72) “as solely drawn to an *in-vitro* method” is maintained, Applicants respectfully submit that it must be interpreted as an election of species requirement such that the subject matter of new claims 90 is that of Group I (because an “*ex vivo*” method necessarily has an “*in vitro*” component to it) while claim 72 is a genus claim linking at least claims 90 and 91.

Moreover, Applicants note that an applicant for a patent has the “right to define what he regards as his invention as he chooses....” *In re Harnisch*, 206 U.S.P.Q. 300, 305 (C.C.P.A. 1980). “[I]f . . . a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim.” *In re Weber*, 198 U.S.P.Q. 328, 331 (Fed. Cir. 1978). Accordingly, as acknowledged in *Ex parte Holt*, the requirement that a singular claim be fragmented into multiple parts is tantamount to a rejection of that claim. See *Ex parte Holt*, 214 U.S.P.Q. 381, 383 (Bd. Pat. App & Int. 1982) (indicating that regardless of the language used by an Examiner to refer to a singular claim as subject to a restriction or rejection under § 121 (due to a purportedly improper Markush claim), “the refusal to examine a claim is, in effect, a rejection of that claim.” *Id.*); see also *In re Haas*, 198 U.S.P.Q. 334 (C.C.P.A. 1978) (determining that § 121 could not be used as the basis for rejecting a single claim or compelling its replacement by a plurality of narrower claims (i.e., restriction within a particular claim) before examination on the merits.).

The fact that claim 72 is a “genus claim” forms the basis for Applicants first traversal of the Restriction Requirement. This follows because the invention of Group I (claim 72) is a “genus” that wholly embraces the inventions of Groups II through V (claims 73-79). Similarly, the invention of Group VI (claim 80) is a “genus” which wholly embraces the inventions of Groups VII through XII (claims 81-89). The inventions of Groups I and VI may thus be viewed as directed to two genera, to which Groups II-V and VII-XII are species, respectively.

It is expressly provided by 37 C.F.R. §1.141(a) that an application may contain “more than one species of an invention” where the application also contains a claim generic to those

species. Accordingly, the Examiner's attention is respectfully directed to 37 C.F.R. §1.146 (and M.P.E.P. 808.01(a) through 809.02) which expressly provides for the handling of claims to a genus and species embraced thereby. Therefore, and regardless of whether the inventions of Groups I-V and VI-XII are "distinct" as alleged in the Restriction Requirement, they are still related inventions (via the genus-species relationship) as set forth at M.P.E.P. 806.04(a) and 806.04(b). This means that Groups I-V (and similarly Groups VI-XII) are not properly subject to restriction from each other as opposed to an election of species requirement.

The second basis of Applicant's traversal is that Group I (claim 72) and Group VI (claim 80) are related as subcombination to a combination such that the standards set forth at M.P.E.P. 806.05 through 806.05(c) apply. This follows because claim 80 is clearly directed to a combination (methods involving *in vivo* or *ex vivo* administration of an altering composition to produce a treatment effect) while claim 72 is clearly directed to the corresponding subcombination of methods involving administration of an altering composition in general. This has been emphasized further by new claims 90 and 91, which indicate different portions of the scope of claim 72. Each of claims 80, 90 and 91 are clearly subcombinations of claim 72.

Therefore, Restriction between claims 72 and 80 can only be supported by following the standards set forth at M.P.E.P. 806.05 through 806.05(c). This has not been done; therefore, no basis supporting Restriction between these claims has been presented.

In light of the above, Applicants respectfully submit that the restriction between Groups I through XII may be withdrawn.

In the event that the instant Restriction Requirement is maintained despite the above discussion, Applicants hereby elect Group I, claim 72 with traverse for the reasons presented above.

Applicants note that when claim 72 is properly recognized as a "genus" claim, then the Examiner's assertion of its scope as limited to "*in vitro*" methods might be modified to be an election of species requirement. In such a case, Applicants elect the species represented by new claim 90, with claim 72 as a claim generic to the elected invention.


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Applicants expressly reserve the right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application. Applicants request examination of the elected subject matter on the merits.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 511582001810. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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